CLAIM SUMMARY DOCUMENT:

Claim 1. (Currently Amended) A process for producing parenterally administrable microparticles containing a biologically active substance, which process comprises:

a) preparing an aqueous solution of the biologically active substance to be incorporated in the microparticles,

b) concentrating the biologically active substance into a highly viscous solution thereof, which has the ability of forming droplets which can be handled at room temperature or into a precipitation thereof in the form of solid particles by mixing the solution obtained in step a) with an aqueous solution of polyethylene glycol ~~(PEG)under such conditions that the biologically active substance is concentrated and/or solidified~~,

c) optionally washing the concentrated ~~and/or solidified~~ biologically active substance obtained in step b),

d) mixing the concentrated ~~and/or solidified~~ biologically active substance obtained in step b) or c) with an aqueous starch solution,

e) mixing the composition obtained in step d) with an aqueous solution of a polymer having the ability of forming a two-phase aqueous system, so as to form an emulsion of starch droplets which contain the biologically active substance as the inner phase in an outer phase of said polymer solution,

f) causing or allowing the starch droplets obtained in step e) to solidify into starch microparticles,

g) drying the starch microparticles from step f), and

h) optionally applying a release controlling shell of a biocompatible and biodegradable polymer to the dried starch microparticles from step f).

Claim 2. (Original) A process according to claim 1, in which step b) is performed such that the solidification of the biologically active substance leads to precipitation of the same.

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Claim 3. (Original) A process according to claim 1, in which step b) is performed such that the solidification of the biologically active substance results in a highly viscous solution, which has the ability of forming droplets which can be handled at room temperature.

Claim 4. (Original) A process according to claim 1, in which step b) is performed to a reversibly solidified active substance.

Claim 5. (Original) A process according to claim 1, in which the solidified biologically active substance forms a pellet or a highly viscous or solid bottom phase in centrifugation or ultracentrifugation.

Claim 6. (Original) A process according to claim 1, in which the polyethylene glycol used in step b) has an average molecular weight of 400-100,000 Da, preferably 4 000-35000 Da, more preferably 6 000-20,000 Da, and most preferably about 20,000 Da.

Claim 7. (Currently Amended) A process according to claim 1, in which the concentration of the polyethylene glycol used in step b) is in the range of 1-50 % (w/w)~~, preferably 2-45 % (w/w), more preferably 10-40 % (w/w), and most preferably 20-30 % (w/w)~~.

B1 cont'd

Claim 8. (Original) A process according to claim 1, in which step d) an aqueous starch solution is utilized, comprising starch which has an amylopectin content exceeding 85% by weight, in which the molecular weight of the said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 10-10 000 kDa.

Claim 9. (Original) A process according to claim 1, in which step d) an aqueous starch solution is utilized, comprising starch which has an amino acid nitrogen content of less than 50 μg per g dry weight of starch.

Claim 10. (Original) A process according to claim 1, in which the starch concentration of the aqueous starch solution used in step d) is at least 20% by weight.

Claim 11. (Currently Amended) A process according to claim 8, in which the starch has a purity of at most 20 μg~~, preferably at most 10 μg, and more preferably at most 5 μg,~~ amino acid nitrogen per g dry weight of starch.

Claim 12. (Currently Amended) A process according to claim 8, in which the starch has an amylopectin content with said reduced molecular weight exceeding 95% by weight~~, preferably exceeding 98% by weight~~.

Claim 13. (Currently Amended) A process according to claim 8, in which the molecular weight of said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 100-4 000 kDa~~, preferably 200- 1 000 kDa, and more preferably 300-600 kDa~~.

Claim 14. (Original) A process according to claim 1, in which the starch is such that it can only be dissolved to a concentration exceeding 25% by weight in water.

Claim 15. (Currently Amended) A process according to claim 1, in which the starch lacks ~~is substantially lacking in~~ covalently bonded extra chemical groups ~~of the types~~ which are found in hydroxyethyl starch.

Claim 16. (Original) A process according to claim 1, in which the starch has an endotoxin content of less than 25 EU/g and contains less than 100 microorganisms per g.

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Claim 17. (Original) A process according to claim 1, in which the starch is essentially purified from surface-located proteins, lipids and endotoxins by means of washing with an aqueous alkali solution and purified from internal proteins by means of ion-exchange chromatography, preferably anion-exchange chromatography.

Claim 18. (Currently Amended) A process according to claim 8, in which in step d) 2-15% by weight amylose is also used as starch, having an average molecular weight within the range of 2.5-70 kDa~~, preferably 5-45 kDa,~~ in which the percentage by weight is calculated on the basis of dry weight starch.

Claim 19. (Original) A process according to claim 8, in which in step d) a solution is prepared having a starch concentration of at least 30% by weight.

Claim 20. (Currently Amended) A process according to claim 8, in which in step d) a solution is prepared having a starch concentration of at most 50% by weight, ~~preferably at most 45% by weight~~.

Claim 21. (Original) A process according to claim 8, in which the aqueous starch solution in step d) is prepared with accompanying autoclaving.

Claim 22. (Currently Amended) A process according to claim 1, in which in step d) the active substance is combined with the starch solution at a temperature of at most 60°C~~, preferably 20-45°C, especially 30-37°C~~.

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Claim 23. (Original) A process according to claim 1, in which in step d) a composition is formed in which the weight ratio between starch and biologically active substance lies within the range of 3:1 to 10 000:1.

Claim 24. (Currently Amended) A process according to claim 1, in which the mixing in step e) is performed at a temperature within the range of 4-50°C~~, preferably 10-40°C, especially 10-37°C~~.

Claim 25. (Original) A process according to claim 1, in which the mixing in step e) is performed by means of at least one static mixer.

Claim 26. (Original) A process according to claim 1, in which in step e) the polymer solution is added to the composition in at least two steps, at least one of the additions being effected after the emulsion has begun to be created.

Claim 27. (Original) A process according to claim 1, in which in step e) polyethylene glycol is used as the aqueous polymer.

Claim 28. (Currently Amended) A process according to claim 27, in which the polyethylene glycol has an average molecular weight of 5-35 kDa~~, preferably 15-25 kDa, especially ca. 20 kDa~~.

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Claim 29. (Currently Amended) A process according to claim 1, in which in step e) starch droplets are formed which give the size required for the microparticles, ~~preferably a mean particle diameter,~~ in the dry state, within the range of 10-200 μm, ~~preferably 20-100 μm, more preferably 20-80 μm~~.

Claim 30. (Original) A process according to claim 29, in which after step e) the microparticles are washed, through filtration, and optionally sieved in order to obtain the desired particle size distribution.

Claim 31. (Original) A process according to claim 1, in which the solidification in step f) is effected at at least two temperatures, in which the initiation is effected at a lower temperature than the termination.

Claim 32. (Currently Amended) A process according to claim 31, in which the solidification is initiated within the range of 1-20°C~~, preferably 1-10°C, especially around 4°C~~, and is terminated within the range of 20-55°C~~, preferably 20-40°C, especially around 37°C~~.

Claim 33. (Currently Amended) A process according to claim 1, in which the drying in step g) is performed in the form of spray-drying, freeze-drying or vacuum-drying~~, preferably freeze-drying~~.

Claim 34. (Currently Amended) A process according to claim 1, in which, as the biologically active substance, a substance is incorporate which is selected ~~chosen~~ from the group consisting of proteins, peptides, polypeptides, polynucleotides and polysaccharides~~, especially recombinantly produced proteins~~.

Claim 35. (Original) A process according to claim 1, in which the application of the release-controlling shell in step h) is performed by means of air suspension technology.

Claim 36. (Original) A process according to claim 1, in which the release-controlling shell in step h) is formed by a homopolymer of copolymer containing alpha-hydroxy acid units.

Claim 37. (Original) A process according to claim 36, in which the alpha-hydroxy acid is lactic acid and/or glycolic acid.

Claims 38-42. (Withdrawn)

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Claim 43. (Canceled)

Claim 44. (Withdrawn)

Claim 45. (Canceled)

Claims 46-59. (Withdrawn)

Claim 60. (New) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 2-45 % (w/w).

Claim 61. (New) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 10-40 % (w/w).

Claim 62. (New) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 20-30 % (w/w).

Claim 63. (New) The process according to claim 11, in which the starch has a purity of at most 10 μg amino acid nitrogen per g dry weight of starch.

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Claim 64. (New) The process according to claim 11, in which the starch has a purity of at most 5 μg amino acid nitrogen per g dry weight of starch.

Claim 65. (New) The process according to claim 12, in which the starch has an amylopectin content with said reduced molecular weight exceeding 98% by weight.

Claim 66. (New) The process according to claim 13, in which the molecular weight of said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 200- 1 000 kDa.

Claim 67. (New) The process according to claim 13, in which the molecular weight of said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 300-600 kDa.

Claim 68. (New) The process according to claim 18, in which in step d) 2-15% by weight amylose is also used as starch, having an average molecular weight within the range of 5-45 kDa in which the percentage by weight is calculated on the basis of dry weight starch.

Claim 69. (New) The process according to claim 20, in which in step d) a solution is prepared having a starch concentration of at most 45% by weight.

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Claim 70. (New) The process according to claim 22, in which in step d) the active substance is combined with the starch solution at a temperature of 20-45°C.

Claim 71. (New) The process according to claim 22, in which in step d) the active substance is combined with the starch solution at a temperature of 30-37°C.

Claim 72. (New) The process according to claim 24, in which the mixing in step e) is performed at a temperature within the range of 10-40°C.

Claim 73. (New) The process according to claim 24, in which the mixing in step e) is performed at a temperature within the range of 10-37°C.

Claim 74. (New) The process according to claim 28, in which the polyethylene glycol has an average molecular weight of 15-25 kDa.

Claim 75. (New) The process according to claim 28, in which the polyethylene glycol has an average molecular weight of ca. 20 kDa.

B' cont'd

Claim 76. (New) The process according to claim 29, in which in step e) starch droplets are formed which give the size required for the microparticles as a mean particle diameter.

Claim 77. (New) The process according to claim 29, in which in step e) starch droplets are formed which give the size required for the microparticles in the dry state, within the range of 20-100 μm.

Claim 78. (New) The process according to claim 29, in which in step e) starch droplets are formed which give the size required for the microparticles in the dry state, within the range of 20-80 μm.

Claim 79. (New) The process according to claim 32, in which the solidification is initiated within the range of 1-10°C, and is terminated within the range of 20-55°C.

Claim 80. (New) The process according to claim 32, in which the solidification is initiated around 4°C, and is terminated within the range of 20-55°C.

Claim 81. (New) The process according to claim 32, in which the solidification is initiated within the range of 1-20°C, and is terminated within the range of 20-40°C.

Claim 82. (New) The process according to claim 32, in which the solidification is initiated within the range of 1-20°C, and is terminated around 37°C.

Claim 83. (New) The process according to claim 33, in which the drying in step g) is performed in the form of freeze-drying.

Claim 84. (New) The process according to claim 34, wherein the protein is a recombinantly produced protein.